

### **REMARKS**

This amendment is responsive to the Office Action dated May 27, 2005. Applicant has amended claims 1 and 9. Claims 1-14 remaining pending.

### **Amendments to the Specification**

Applicant has amended paragraphs [0010], [0025], [0028], [0030], [0036], [0044] and [0050] to correct typographical errors, and provide serial numbers for co-pending applications referenced in the specification. No new matter is added by these amendments.

### **Claim Rejections Under 35 U.S.C. §§ 102 and 103**

In the Office Action, the Examiner rejected claims 1-10, 13 and 14 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,176,879 to Reischl et al. (Reischl), or alternatively under 35 U.S.C. § 103(a) as being unpatentable over Reischl in view of U.S. Patent No. 5,489,225 to Julian et al. (Julian). The Examiner also rejected claims 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Reischl in view of Julian. Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the amended claims. Reischl fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and neither Reischl nor Julian provides any teaching that would have suggested the desirability of modification to include such features, as required by 35 U.S.C. 103(a).

#### *Claims 1-8*

For example, Reischl fails to teach or suggest an implantable medical device comprising at least two interconnected modules, each of the modules comprising a respective one of at least two housings, as recited by Applicant's independent claim 1, as amended. Instead, as clearly indicated in the portion cited by the Examiner, Reischl describes an implantable medical device that has a single, unitary housing 11, with two portions 12 and 13 made of different materials.<sup>1</sup> Throughout the disclosure, Reischl consistently depicts and describes the implantable medical

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<sup>1</sup> See Reischl, column 3, lines 35-38.

device as having a single housing.<sup>2</sup> The single housings of many implantable medical devices, like the single housing of the implantable medical device described by Reischl, i.e., are formed by joining two portions during manufacture of the implantable medical device.<sup>3</sup> Such housing portions, whether or not made of different materials, are not respective housings, as required by claim 1.

With respect to this limitation of claim 1, the Examiner argued that the Reischl device “is considered to anticipate[s] the claimed interconnected modules and housing because both configurations accept external leads and have a low profile and allow for deployment proximate to a treatment or monitoring site.” Even if the Examiner’s characterization of the Reischl device were correct, this argument is irrelevant. Applicant respectfully reminds the Examiner that, in order to support an anticipation rejection under 35 U.S.C. 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the “all-elements rule.”<sup>4</sup> If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. 102(b) is improper.<sup>5</sup> In other words, the Examiner can only “consider” Reischl to anticipate independent claim 1 if it discloses each and every element of claim 1.

Reischl also fails to teach or suggest an overmold that at least partially encapsulates each of at least two housings, as required by amended independent claim 1. In reference to this requirement of claim 1, the Examiner cited the description within Reischl of a silastic jacket and a rigid material surrounding a housing.<sup>6</sup> However, the silastic jacket is discussed in the background section of Reischl as being part of a different, existing implantable medical device, and Reischl never suggests that such a component may be used as part of the implantable medical device described therein. Indeed, Reischl suggests that the housing of the implantable medical device described therein overcomes a number of problems associated with the silastic

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<sup>2</sup> See, e.g., Reischl, FIGS. 1-5 and consistent references to “a housing” and “the housing” throughout the specification.

<sup>3</sup> See Reischl, column 2, lines 49-52.

<sup>4</sup> See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) (“it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention”).

<sup>5</sup> *Id.* See also *Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

<sup>6</sup> See Reischel, column 1, lines 35-55, column 2, lines 49-57.

jacket, and thereby teaches away from use of a silastic jacket with the implantable medical device described therein.<sup>7</sup>

Moreover, Reischl does not even suggest that the silastic jacket may be used to at least partially encapsulate each of at least two housings, as required by claim 1. Instead, Reischl merely indicates that the silastic jacket interacts in some fashion with a single housing.<sup>8</sup> The only function for the silastic jacket described in Reischl is forming a thin, flexible flap, which extends from one side of a housing, and holds a receiving coil and a magnet.<sup>9</sup> This function would not be facilitated or furthered by partially encapsulating each of at least two housings, as required by claim 1.

Further, contrary to the Examiner's argument, Reischl does not disclose or suggest a rigid material that surrounds a housing. The portion of Reischl cited by the Examiner as describing the rigid material merely discusses the housing for the device described therein, and does not mention any rigid material, or any material that surrounds the housing.<sup>10</sup> Further, the only use of the word "rigid" in Reischl is with reference to the housing.<sup>11</sup> Accordingly, Applicant respectfully requests clarification as to what "rigid material" the Examiner is referring.

Additionally, the Examiner argued that "[t]he disclosed silastic jacket and the rigid material surrounding the housing is considered to anticipate the claimed overmold because all configurations hold the modules and housing in a fixed position relative to one another and can be made of a variety of materials that are flexible or rigid." Applicant respectfully suggests that the Examiner is mischaracterizing the Reischl disclosure, and requests that the Examiner identify support within in the Reischl disclosure for this statement. Reischl does not even appear to describe a rigid material that surrounds a housing, and does not suggest that the silastic jacket "hold[s] the modules and housing in a fixed position relative to one another and can be made of a variety of materials that are flexible or rigid."

As discussed above, the only function for the silastic jacket described in Reischl, which appears completely unrelated to that which the Examiner has stated, is forming a thin, flexible

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<sup>7</sup> See Reischl, column 1, lines 34-56.

<sup>8</sup> *Id.*

<sup>9</sup> See Reischl, column 1, lines 34-56.

<sup>10</sup> See Reischl, column 2, lines 49-57.

<sup>11</sup> See Reischl, column 2, line 30.

flap, which extends from one side of a housing, and holds a receiving coil and a magnet.<sup>12</sup> Moreover, “holding the modules in a fixed position relative to one another” and whether the materials are flexible or rigid are not elements of claim 1. Again, the Examiner can only “consider” Reischl to anticipate independent claim 1 if it discloses each and every element of claim 1.

Reischl also fails to disclose or suggest an overmold that comprises a lead connection module configured to accept an external lead, as required by independent claim 1. It does not appear that the Examiner addressed this requirement of claim 1. In any event, even if the silastic jacket could be improperly construed to otherwise meet the requirement of an overmold in claim 1, Reischl does not even remotely suggest that the silastic jacket comprises a lead connection module configured to accept an external lead. Instead, Reischl teaches only that the silastic jacket holds a receiving coil and a magnet.<sup>13</sup>

Julian does not provide any teaching or suggestion that would have overcome the above-identified deficiencies of Reischl with respect to independent claim 1. In particular, Julian does not teach or suggest at least two interconnected modules, each of the modules comprising a respective one of at least two housings, or an overmold that at least partially encapsulates each of at least two housings and includes a lead connection module. Instead, Julian describes an implantable medical device with a single housing, and a header on the housing that includes a lead connector.

The Examiner argued that it would have been obvious to one of ordinary skill in the art to combine the implantable medical device teachings of Reischl with the lead connection configuration found in Julian for the purpose of electrically and mechanically coupling the lead to the components of the implantable medical device. However, because neither Reischl nor Julian discloses the above-identified limitations of claim 1, the combination proposed by the Examiner would still fail to render claim 1 obvious.

Moreover, it is entirely unclear from the Office Action how the Examiner proposes that Reischl and Julian be combined. Reischl already discloses structures to electrically and mechanically couple cables to the described implantable medical device. Accordingly, a mere

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<sup>12</sup> See Reischl, column 1, lines 34-56.

<sup>13</sup> See id.

desire to electrically and mechanically couple cables to an implantable medical device would not have motivated one of ordinary skill in the art to substitute the lead connection configuration of Julian for those structures, if that is what the Examiner is proposing. Further, there is no teaching in either Reischl or Julian that would have provided one of ordinary skill with a suggestion or motivation to include the lead connection disclosed by Julian in the silastic jacket described by Reischl, or a belief that such a modification would be reasonably likely to be successful, if that is what the Examiner is suggesting. Indeed, one of ordinary skill in the art would have likely considered such a modification as potentially interfering with the coil held in the silastic jacket, and therefore would have consciously avoided such a modification.

With respect to claims 3, as another example, Reischl fails to teach or suggest an overmold that comprises a first material and a second material, wherein the lead connection module is deployed within the first material. Further, Reischl fails to teach or suggest that the first material comprises a non-elastomeric material, as required by claim 4. The Examiner appears to have misunderstood the requirements of these claims.

In particular, in support of the rejection of these claims, the Examiner cited portions of Reischl that describe the ceramic and metallic materials of a device housing.<sup>14</sup> However, the requirements of claims 3 and 4 are directed to materials of an overmold that at least at least partially encapsulates each of a plurality of housings. Consequently, the teachings in Reischl relating to the materials of a device housing are irrelevant to the requirements of claims 3 and 4.

In rejecting independent claim 1, the Examiner argued that the silastic jacket described in the background section of Reischl meets the requirement of an overmold. For the reasons discussed above, Applicant disagrees with this argument. Moreover, even if the silastic jacket could be improperly construed to otherwise meet the requirement of an overmold, Reischl does not even suggest that the silastic jacket comprises first and second materials, with a lead connection module deployed in the first material, as required by claim 3. Further, Reischl does not suggest that the silastic jacket comprises a non-elastomeric material, as required by claim 4. Indeed, the term "silastic," which refers to a soft, pliable plastic, is entirely inconsistent with this requirement of claim 4. Julian does not provide any teaching or suggestion that would overcome these deficiencies of Reischl with respect to claims 3 and 4.

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<sup>14</sup> See Reischl, column 3, lines 50-60, column 4, lines 50-55.

In sum, Reischl fails to disclose each and every feature set forth in claims 1-8, and neither Reischl nor Julian provides any teaching that would have suggested modification to include such features. For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-8 under 35 U.S.C. §§ 102(b) or 103(a). Withdrawal of these rejections is requested.

*Claims 9-14*

For the reasons discussed above with reference to independent claim 1, the applied references fail to disclose or suggest a lead connection module deployed within an overmold, as required by independent claim 9. Further, for the reasons discussed above with reference to claim 3, the applied references fail to disclose or suggest an overmold comprising a first material configured to hold at least one of a plurality of housings, and a second material coupled to the first material, as required by independent claim 9. For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 9-14 under 35 U.S.C. §§ 102(b) or 103(a). Withdrawal of these rejections is requested.

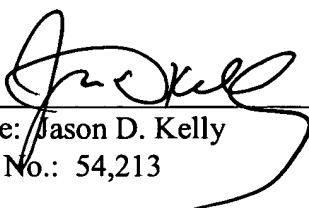
**CONCLUSION**

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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